SECTION E – 510(K) SUMMARY

JAN 18 2008

(As Required By 21 CFR 807.92)

Submitter Information

Company: MicroMRI, Inc.
1429 Walnut Street, Suite 1102
Philadelphia PA 19102
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Device Information

Device Name: MicroMRI Wrist Coil
Common Name: Magnetic Resonance Coil
Classification: Magnetic Resonance Imaging System
Product Code: 90 MOS, Class II (21CFR892.1000)

Predicate Devices

The MicroMRI Wrist Coil system for scanning human wrist is significantly equivalent to the currently marketed BC-10 1.5T (Mayo Clinic) wrist coil and HRW Array Coil (Invivo Corporation).

Device Description

The MicroMRI Wrist Coil uses an elliptical birdcage design to provide the highest possible signal-to-noise ratio (SNR) for imaging a human wrist. The two piece structure facilitates the use of the coil for a wide range of wrist sizes. The elliptical design and ability to conform to the subject's wrist makes the coil unique and efficient in transmitting and receiving the RF signal to the anatomy (i.e., the wrist).

The accompanying immobilization system provides a means to stabilize the patient's arm during the scan. The immobilization system provides a means for positioning the patient's arm consistently in the same position and orientation.

Intended Use

The MicroMRI Wrist Coil is a transmitting and receiving device to be used in conjunction with GE Healthcare and Siemens 1.5T MRI systems to image the wrist. The images acquired using the MicroMRI Wrist Coil along multiple axes (axial, coronal, sagittal, and oblique) are a measure of the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the spatial image are proton density, spin-lattice (T1) and spin-spin (T2) relaxation times, flow velocity and chemical shift. These wrist MRI images when interpreted by a trained

physician can be useful in determining a diagnosis. The MicroMRI Wrist Coil cannot be used with an MRI system that supports the use of only receive coils.

Predicate Comparison

The MicroMRI Wrist Coil is comparable to BC-10 1.5T wrist coil with the primary difference being that the BC-10 has the ability to scan the hand and wrist. The MicroMRI Wrist Coil is designed specifically to scan only the wrist.

The MicroMRI Wrist Coil is comparable to HRW Array Coil with the primary difference being that the HRW Array Coil is a receive only coil. The MicroMRI Wrist Coil utilizes a quadrature birdcage design and can transmit and receive RF signals, requiring less power.

Summary of Performance Testing

The performance testing of MicroMRI's Wrist Coil was conducted in accordance with the NEMA standards, and IEC/UL/CSA/EN 60601-1 standards. The performance test results indicate that the MicroMRI Wrist Coil is comparable to the predicate devices.

Conclusions

MicroMRI considers the MicroMRI Wrist Coil to be substantially equivalent to both Mayo Clinic BC-10 1.5T and Invivo HRW Array Coil. MicroMRI Wrist Coil does not include any new indications for use or present any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2008

Mr. Hrishikesh Gadagkar
Vice President of Engineering and Manufacturing
MicroMRI, Inc.
1429 Walnut Street, Suite 1102
PHILADELPHIA PA 19102

Re: K073131
Trade/Device Name: MicroMRI Wrist Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 2, 2007
Received: November 7, 2007

Dear Mr. Gadagkar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION D – STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): NA

Device Name: MicroMRI Wrist Coil

Indications for Use:

The MicroMRI Wrist Coil is a transmitting and receiving device to be used in conjunction with GE Healthcare and Siemens 1.5T MRI systems to image the wrist. The images acquired using the MicroMRI Wrist Coil along multiple axes (axial, coronal, sagittal, and oblique) are a measure of the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the spatial image are proton density, spin-lattice (T1) and spin-spin (T2) relaxation times, flow velocity and chemical shift. These wrist MRI images when interpreted by a trained physician can be useful in determining a diagnosis. The MicroMRI Wrist Coil cannot be used with an MRI system that supports the use of only receive coils.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073131